IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 20-1744-CFC
v.	)	
	)	
WALMART INC. and WAL-MART STORES EAST, LP,	)	
	)	
	)	
Defendants.	)	

BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTEREST OF *AMICUS CURIAE*

Pharmacists play a critical role in our nation's health care system, daily ensuring that millions of patients receive the medicines they need and instructions for safely using them. Whether in independent pharmacies or chain drug stores, pharmacists and their employers share the same mission: to deliver to patients the medicines that licensed practitioners have determined they need.[1]

The National Association of Chain Drug Stores ("NACDS") is a leader in that mission. A non-profit, tax-exempt organization incorporated in Virginia, NACDS represents traditional drug stores, community pharmacies, supermarkets, and mass merchants with pharmacies. NACDS chain members operate over 40,000 pharmacies and employ nearly 3 million individuals, including 155,000 pharmacists; its 80 chain member companies include regional chains, with a minimum of four stores, and national companies. NACDS members also include more than 900 supplier partners and over 70 international members in 21 countries.

NACDS's primary interests in this case are to maintain and enhance the safe care of patients who rely on pharmacists' training, judgment, and professionalism, and to ensure that pharmacists can practice their profession under clear and consistent rules, without the threat of severe penalties just for doing their jobs.

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[1] While healthcare professionals other than physicians have prescribing authority, for the sake of simplicity this brief refers to prescribing "physicians."

INTRODUCTION

The devastating effects of America's opioid epidemic have triggered a range of efforts to combat the abuse of controlled substances. Although it is commonly recognized that pharmacists and pharmacies were not responsible for the crisis,[2] NACDS members are doing their part to prevent the diversion of prescription medications, reduce drug abuse, and save lives. Unfortunately, the government's response to the crisis—in particular, its targeting of pharmacists and pharmacies in cases like this one—is undermining pharmacists' ability to care for their patients.

In the last year, the Department of Justice ("DOJ") has initiated a barrage of enforcement actions in federal courts across the country, accusing pharmacists and pharmacies of unlawfully dispensing medicines—even though the prescriptions they filled were facially valid and written by physicians licensed by their states and registered by the Drug Enforcement Administration ("DEA"). Because the Controlled Substances Act ("CSA") and its implementing regulations impose liability only on pharmacists who "knowingly" fill a prescription issued outside "the usual course of professional treatment," 21 C.F.R. § 1306.04(a), the government's suits against pharmacists (and pharmacies) rely on novel theories of liability that seek to evade or eliminate that knowledge requirement. These theories

[2] Robert J. Blendon & John M. Benson, *The Public and the Opioid-Abuse Epidemic*, 378 NEW. ENG. J. MED. 407, 410 (2018).

have no legal basis. Indeed, § 1306.04(a)'s knowledge requirement was added specifically to avoid enforcement scenarios like this one.

The government's recent enforcement efforts are of great concern to NACDS. They sweep broadly—far beyond the targeted wrongdoer who knowingly fills an illegitimate prescription, and far beyond this case. The government's approach traps pharmacists (and the pharmacies that employ them) in an untenable position with respect to every facially valid prescription a patient presents. On one hand, filling a prescription that, in the government's opinion, raises a "red flag," could bring civil and criminal liability—even when the pharmacist is acting in good faith. On the other hand, the threat of liability for filling such a prescription pressures a pharmacist to override a physician's medical judgment, second-guess a prescription's appropriateness, and refuse to fill it. Refusing to fill such a prescription could generate disciplinary actions by licensing boards, as well as lawsuits by the prescribing physicians and the patients deprived of their prescribed medicines. More troubling still, often the prescriptions subject to refusal under the government's theory are, because of the nature of "red flags," written for patients who most need access to opioids to mitigate painful conditions.

The government's overreach has potential not only to confuse pharmacists, but to chill their use of professional discretion, threatening their patients' lives and health. The Court should reject the government's theories and dismiss this case.

ARGUMENT

I. Reflecting the different roles played by physicians and pharmacists, § 1306.04 imposes liability only on pharmacists who "knowingly" fill an illegitimate prescription.

A. Pharmacists are not authorized by law or prepared by training to supersede physicians' medical judgment in prescribing controlled substances.

Pharmacists occupy a unique role in our health care system. With different licenses, education, skill sets, responsibilities, and workplaces from physicians, pharmacists play a vital but distinct role in a patient's care. Trained to understand how medicines affect the human body and interact with other medicines, pharmacists do not diagnose patients and cannot prescribe medication. When a pharmacist dispenses a controlled substance to a patient, as prescribed by a physician, the pharmacist does so based on the *physician*'s assessment of the patient's needs. The pharmacist has not examined or diagnosed the patient, and lacks the context the physician has regarding the patient's medical situation, records, and history. While pharmacists must comply with a myriad of state and federal statutes and regulations—and may face liability if they do not—these rules do not authorize, much less require, them to supersede the medical judgment of the prescribing physician.[3]

[3] In addition to complying with the CSA and numerous other federal laws and regulations, pharmacists must also comply with their state's laws, such as Delaware's Uniform Controlled Substances Act, 16 DEL. CODE § 4701 *et seq.*, and Uniform Controlled Substances Act Regulations, 24 DEL. ADMIN. CODE CSA 1.0

The CSA recognizes pharmacists' circumscribed role in dispensing controlled substances. It provides that pharmacists may not dispense Schedule II controlled substances "without the written prescription of a practitioner," 21 U.S.C. § 829(a), and that they risk criminal and civil liability if they do, *see id.* §§ 841(a), (c), 842. The CSA's implementing regulations likewise explain that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The regulations separately provide that such a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed" by a registered entity. 21 C.F.R. § 1306.06. Federal law says little about pharmacists' role in this context, and even less about their employers.

B. By design and express text, § 1306.04 protects pharmacists who do not "knowingly" fill invalid prescriptions.

Consistent with the division of responsibility between physicians and pharmacists, § 1306.04 limits when pharmacists may be held liable for filling prescriptions to situations where a pharmacist *knows* a prescription is illegitimate:

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et seq. Pharmacists are subject to strict state-imposed regulations as well as educational and licensing requirements enforced by state boards of pharmacy. *See, e.g.*, 24 DEL. ADMIN. CODE § 2500 *et seq.*

> The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person ***knowingly*** filling such a ***purported*** prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). Notwithstanding her "corresponding responsibility," a pharmacist may only be held liable for penalties if she "*knowingly* fill[s]" a "purported" prescription—*i.e.*, a prescription that was not written "in the usual course of professional treatment." *Id.* (emphasis added).

These critical limitations on the pharmacist's liability under § 1306.04 are no accident. They were added to the regulation intentionally and purposely to avoid scenarios like those the government is creating with this and other lawsuits. When first proposed in 1971, the regulation lacked the word "knowingly," which would have allowed penalties for any "person filling [an illegitimate] prescription." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4847, 4948 (Mar. 13, 1971). Pharmacists protested such an expansive rule, however, for the reasons discussed above. During the comment period, the National Association of Retail Druggists (now known as the National Community Pharmacists Association) specifically "objected to the responsibility placed upon a pharmacist under § [1306.04] to

determine the legitimacy of a prescription." *Comments and Objections to Part 306*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). As a result of these objections, the regulation's "language [was] revised to require knowledge." *Id.*

These limitations on liability sensibly reflect the very real constraints on pharmacists presented with prescriptions for controlled substances. To be sure, pharmacists inspect prescriptions for indicia of facial invalidity to determine if they can be filled—*e.g.*, tampering, missing or incorrect information, a forged signature, or a prescribing physician who is not DEA-registered. *See* 21 C.F.R. § 1306.05(a). When presented with a facially valid prescription, however, a pharmacist lacking knowledge of the patient's background and diagnosis cannot be expected to second-guess the physician's determination that the prescribed medicine is appropriate, and to obstruct the patient's medical care by withholding it. The knowledge requirement in § 1306.04 properly reflects this circumscribed role.

II. The government's attempts to sidestep § 1306.04's knowledge requirement lack a valid legal basis and penalize innocent conduct.

A. The government aims to evade the knowledge requirement.

All three of the government's theories of liability improperly attempt to read § 1306.04's knowledge requirement out of the regulation.

First, the government targets pharmacists filling prescriptions that allegedly presented so-called "red flags"—factors that have nothing to do with a prescription's facial validity but instead, in the government's opinion, suggest the

physician may have written it for an illegitimate purpose. The "red flags" the government points to here include: patients paying for prescriptions in cash, Compl. ¶ 330; patients from a different state than the prescribing physician or dispensing pharmacy, Compl. ¶ 425; patients seeking "early refills," Compl. ¶ 274; and certain combinations of prescribed drugs, Compl. ¶ 320. The government has cited these and numerous other "red flags" in recent cases against other pharmacies and pharmacists across the country.[4] The government asserts that, when faced with a prescription presenting one or more unresolved "red flags," a pharmacist ***must*** second-guess its appropriateness, override the physician's medical judgment, and refuse to fill it—or else face liability. *See* Compl. ¶ 78.

The government's theory has no legal basis. First, neither the CSA, nor its implementing regulations, nor the most recent version of DEA's Pharmacist's Manual contains any requirement that pharmacists not fill any prescription

[4] *See, e.g.*, Compl. ¶ 72, *United States v. Howen*, No. 1:21-cv-00106-DAB-SAB (E.D. Cal. Jan. 26, 2021) (late filling of prescriptions); Compl. ¶ 28, *United States v. Larchmont Pharmacy, LLC*, No. 2:20-cv-04999-JD (E.D. Pa. Oct. 8, 2020) (different individuals present similar prescriptions "at approximately the same time"); Compl. ¶ 79, *United States v. Ridley's Family Markets, Inc.*, No. 1:20-cv-00173-TS-JCB (D. Utah Dec. 4, 2020) ("[n]ew prescriptions for controlled substances a patient has never received before"); Compl. ¶ 67, *United States v. Shaffer Pharmacy*, No. 3:21-cv-00022-JZ (N.D. Ohio Jan. 6, 2021) (providing refills when "one to three days of supply remained"); Compl. ¶ 66, *United States v. WeCare Pharmacy, LLC*, No. 8:21-cv-00188-MSS-AEP (M.D. Fla. Jan. 26, 2021) (dispensing same medications "for the same patients over long periods of time").

presenting one or more "red flags." Indeed, these sources do not mention "red flags" at all, let alone provide specific examples of them.[5] Unable to cite a single statute or regulation, the government instead weakly asserts that the responsibility to identify and resolve "red flags" is "well recognized" and "discussed in the training of pharmacists, by pharmacists at professional conferences, and in training materials prepared by pharmacy boards," Compl. ¶ 85—as if a failure to follow "training materials" equates to knowingly filling invalid prescriptions. It does not. Alarmingly (but predictably), the absence of written law underpinning the government's "red flags" theory has allowed it to apply its theory inconsistently.[6]

Second, the government attempts to penalize, under *federal* regulation 21 C.F.R. § 1306.06 (requiring pharmacists to fill prescriptions "in the usual course . . . of professional practice"), a pharmacist's failure to comply with any *state* regulation or professional norm. *See* Walmart Br. 23–26; Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020) (alleging the "usual course of pharmacy practice includes compliance with all relevant state

[5] By contrast, the regulations do provide specific standards for the elements of a valid prescription, *see, e.g.*, 21 C.F.R. § 1306.05(a), removing them—unlike "red flags"—from the realm of professional judgment and debate.

[6] *Compare* Compl. ¶¶ 375-76 (alleging that the "combination of an immediate-release opioid and methadone," "a longer-acting drug," raises "obvious red flags"), *with* Compl. ¶ 99, *United States v. Bacaner*, No. 8:21-cv-391 (M.D. Fla. Feb. 19, 2021) ("In a legitimate pain management practice, an extended release ("ER") opioid generally accompanies an [immediate-release] opioid[.]").

laws and regulations"). The government presents no support for this novel proposition, which elevates § 1306.06's significance for the sole purpose of attempting to sidestep § 1306.04's knowledge requirement and its requirement that a prescription be illegitimate before a pharmacist can be held liable. In any event, the enforcement and interpretation of the regulatory regimes governing the practice of pharmacy in each state are beyond DEA's and DOJ's jurisdiction.

Third, the government proposes to show a CSA violation by mixing and matching what individual pharmacists know—for instance, by imputing the "knowledge" of a pharmacist who refuses to fill a prescription to another pharmacist who fills that prescription (or another written by the same physician). *See, e.g.*, Compl. ¶ 24; Walmart Br. 6–13. The Court should also reject this unsupported end-run around § 1306.04's requirement to prove that a specific pharmacist knowledge filled an invalid prescription.

B. The government's theories of liability penalize innocent conduct.

The government's theories of liability sweep far too broadly.[7] Creating federal liability for departing from any state regulation or professional norm would be an alarming and unprecedented overreach, as would endorsing the government's

[7] *See, e.g.*, Mot. for a Prelim. Inj. at 17, *United States v. Bacaner*, No. 8:21-cv-391 (M.D. Fla. Feb. 19, 2021) (arguing that "a pharmacy or pharmacist dispensing controlled substances despite unresolved red flags is not saved if some of those prescriptions happen to have been issued based on bona-fide doctor-patient relationships for conditions warranting the prescriptions").

baseless theory of "collective knowledge." Even the government's categorical condemnation of prescriptions with "red flags" goes too far. That approach completely ignores the individualized, case-by-case approach that pharmacists take when filling prescriptions. *See Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (noting that "each case must be evaluated based on its own merits in view of the totality of circumstances"). Many of the so-called "red flags" the government cites as bases for liability could have legitimate explanations, medical or otherwise. A cash-paying patient might lack insurance coverage; a pharmacist practicing in a vacation spot may often fill prescriptions from out-of-state patients; and a patient seeking a refill days before her existing supply ends may simply be planning ahead. Such examples demonstrate the dangerous folly of a categorical approach to culpability.

The government itself has trouble defending its categorical approach. Take, for instance, its criticism of "trinity combinations" of drugs. Compl. ¶¶ 384–86. The government says that, "on their face," such prescriptions are "not issued for a legitimate medical purpose or in the usual course of practice," and that Walmart's pharmacists knew that "substantially all" of the prescriptions were invalid. Compl. ¶ 407. Even if one accepts this allegation as true, despite its lack of support, "substantially all" is not the same as "all." The government's own characterization acknowledges that categorical treatment is over-inclusive—a fact DEA admitted in

correspondence with NACDS eighteen months ago. In one of the first cases under its newly expansive theories, the government had claimed "[t]here is no medical basis for the simultaneous prescription of any version of the three 'trinity' drugs." Compl. ¶ 31, *United States v. Rodriguez*, No. 19-cv-1055 (N.D. Tex. May 2, 2019). When NACDS questioned that assertion, DEA declined to defend it, saying instead that it "is up to each DEA-registered practitioner to treat a patient according to his or her professional medical judgement." Letter from Dep. Asst. Adm'r Prevoznik, DEA to Kevin N. Nicholson, NACDS (Nov. 4, 2019), https://tinyurl.com/gs2lvf5y.[8] Just so. Unlike the government's litigation position, DEA's response recognizes that assessing unique patient circumstances and counselling patients about the risk of drug interactions (as when taken in combinations) on a case-by-case basis is what pharmacy practice is all about—not overriding the medical judgment of licensed and registered physicians.[9]

[8] The government has similarly contradicted itself with respect to high-dosage prescriptions. *Compare* Compl. ¶ 75, *United States v. Chip's Discount Drugs, Inc.*, No 2:20-cv-00010-LGW-BWC (S.D. Ga. Feb. 12, 2020) (doses above a "90 MME/day benchmark" are *necessarily* illegitimate), *with* 71 Fed. Reg. at 52720 (dosage "can vary greatly from patient to patient"; what "might be blatantly excessive" in one case may be "insufficient" in another).

[9] *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, *CDC Advises Against Misapplication of the* Guideline for Prescribing Opioids for Chronic Pain (Apr. 24, 2019) (emphasizing "individualized assessment" and "the specific circumstances and unique needs of each patient"), https://tinyurl.com/yxjmsazg.

III. The government's enforcement efforts force pharmacists into an untenable position and create unnecessary confusion.

A. Pharmacists face potential professional and legal liability when they decline to fill facially valid prescriptions.

The government's theory of liability leaves pharmacists (and the pharmacies who employ them) in a precarious spot. On one hand, they may face liability if they *fill* facially valid physician-ordered prescriptions. On the other hand, as discussed below, they may face professional and civil liability if they *refuse to fill* such prescriptions.

Physicians have long bristled at pharmacists' efforts to verify the appropriateness of prescriptions, even when DEA has triggered those efforts. *See* Am. Med. News, *AMA meeting: Pharmacists warned on intruding into prescribing decisions* (July 1, 2013), https://tinyurl.com/y3kyaxz4. Nevertheless, in 2013 the American Medical Association adopted a resolution, still in place today and known in the industry as the "don't call us, we'll call you" resolution: it condemns "inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions, diagnoses and treatment plans [as] an interference with the practice of medicine and unwarranted."[10] When pharmacists have followed DEA's

[10] AMA Resolution 218: AMA Response to Pharmacy Intrusion into Medical Practice (2013), https://tinyurl.com/y6zawncj. *See also id.* (condemning "inappropriate pharmacist prescription verification requirements" and calling for "legislative and regulatory solutions to prohibit pharmacies and pharmacists from denying medically necessary and legitimate therapeutic treatments to patients").

suggested approach and declined to fill prescriptions, state medical boards have threatened legal or disciplinary action against them for engaging in the unauthorized practice of medicine. The head of Texas's medical board, for instance, warned that no pharmacy's "[g]uideline should override a physician's ability to prescribe meds. That would be the unlicensed practice of medicine. . . . The [Texas Medical Board] wants to know when this happens." Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://tinyurl.com/y5cs5rpz. DOJ's enforcement approach, however, forces pharmacists into that position.

Individual physicians, too, have threatened tort liability against pharmacists who decline their prescriptions. As one physician-plaintiff explained in claiming defamation, "failure to fill his patient's prescriptions necessarily imputed illegal conduct because pharmacists are required to fill prescriptions unless the [p]harmacist has reason to know of some irregularity." *Reasor v. Walmart Stores E., L.P.*, No. 3:19-CV-27-CRS, 2019 WL 5597302, at *3 (W.D. Ky. Oct. 30, 2019) (internal quotation omitted). Similar cases abound. *See, e.g.*, *Lefrock v. Walgreens Co.*, 77 F. Supp. 3d 1199 (M.D. Fla. 2015), *aff'd*, 644 F. App'x 898 (11th Cir. 2016).

Licensing boards also have discouraged pharmacists from refusing prescriptions, citing patients' health demands and urging that "[e]xtreme caution should be used when deciding not to fill a prescription." Letter from Richard Holt,

Chair, Alaska Board of Pharmacy (Jan. 23, 2019), https://tinyurl.com/y6baplgv; *see also* N.H. Board of Pharmacy, Board Notice (May 31, 2018), https://tinyurl.com/y5ag5dof. This pressure is more than rhetorical: licensing boards have threatened pharmacists and pharmacies with serious discipline for refusing to dispense controlled substances. The Wisconsin Pharmacy Examining Board provides one of many examples. It found "evidence of professional misconduct" by a pharmacy that, because of concerns of overprescribing, had decided it would no longer fill controlled substance prescriptions from a local clinic. Wis. Pharmacy Examining Bd., *Administrative Warning*, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018) [Ex. 2, Walmart's Mot. for Summ. J., *Walmart Inc. v. DEA*, No. 4:20-cv-00817-SDJ (E.D. Tex. Nov. 13, 2020), ECF No. 19-3]. Concluding that the pharmacy's decision had deterred its pharmacists "from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order," the board issued the pharmacy an administrative warning—and emphasized that "any subsequent similar violation may result in disciplinary action." *Id.*

Lastly, patients themselves have sued pharmacies, under federal and state law, for refusing prescriptions. Two recent class action lawsuits, for instance, claim violations of the ADA and the Rehabilitation Act for refusal to fill "valid and legal prescriptions for opioid medication." Compl. ¶ 2, *Smith v. Walgreens Boots All.,*

Inc., No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020) [hereinafter *Smith*]; Compl. ¶ 2, *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020). *Smith* alleges that Walgreens "purport[s] to comply with federal mandates and the CDC Guidelines for opioid prescriptions," but its use of a "'Good Faith Dispensing' checklist in connection with opioid prescriptions . . . stigmatizes and discriminates against chronic pain patients," through no fault of their own "or of the doctors caring for them." Compl. ¶ 55, *Smith.*

In sum, pharmacists are caught between a rock and a hard place. The Court should not squeeze them closer together by validating the government's theory.

B. The government's approach creates confusion and threatens to chill pharmacists in doing their jobs.

Unless rejected, the government's expansive theories of liability will continue to breed confusion in an area that demands clarity, making pharmacists' jobs virtually impossible. With no statutory or regulatory text guiding or constraining the government's enforcement efforts, the courts must provide a backstop.

In the meantime, pharmacists (and the pharmacies that employ them) will continue to face uncertain legal risk. Lacking clarity about their legal duties when filling prescriptions—*i.e.*, an essential function of their jobs—hamstrings pharmacists. Rejection of the government's theories of liability would provide clarity and relief for the profession, especially those individual pharmacists and

independent pharmacies who lack the resources themselves to navigate the regulatory and litigation uncertainty. Pharmacists deserve to practice their profession, serve their patients, and fill facially valid prescriptions free from anxiety that they will later be found to have violated federal law in doing so.

Finally, a decisive dismissal is necessary because the consequences of the government's legal position fall most heavily on the patients whose prescriptions needlessly go unfilled. The natural effect of the government's approach is to chill the conduct of pharmacists in filling prescriptions, including valid ones, thereby leaving patients in the lurch and without the medicines they need. This is no hypothetical concern, as illustrated by the patient suits described above and as confirmed by researchers.[11]

CONCLUSION

NACDS and its members remain willing to comply with regulations that clearly and consistently define their legal obligations in filling prescriptions for controlled substances. But no existing regulation, or any other law, supports the government's positions here. The Court should dismiss this case.

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[11] *See, e.g.*, Hannah L.F. Cooper, et al., *Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky*, 85 INT'L J. OF DRUG POL'Y 102701 (2020) (aggressive enforcement efforts have caused pharmacies to restrict patients' access to medicine used to treat opioid dependence, because they fear being reported to DEA for "suspicious" orders), https://doi.org/10.1016/j.drugpo.2020.102701.

Respectfully submitted,

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WORD COUNT CERTIFICATION

The undersigned hereby certifies that this filing complies with the type, font, and word limitations set forth in this Court's Standing Order Regarding Briefing In All Cases, in that it was prepared in Times New Roman 14-point font and contains 3,995 words (exclusive of the cover page, table of contents, table of authorities, and signature block), as determined by the word-count feature of Microsoft Word.

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